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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,049	06/20/2007	Jody Stallings	50642/335252	8962
30559	7590	01/13/2010		
DIANA HOUSTON SMITH & NEPHEW, INC. 1450 BROOKS ROAD MEMPHIS, TN 38116			EXAMINER FONTENOT, NIGEL RAI	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 01/13/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/594,049	<b>Applicant(s)</b> STALLINGS ET AL.	
	<b>Examiner</b> NIGEL FONTENOT	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,9,12,15 and 17-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,9,12,15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This action is responsive to the Amendments/Arguments filed 10/12/2009.

Claims 3, 7, 10-11, 13-14, and 16 have been canceled. Claims 1, 5, 9, 12, and 15 have been amended. Newly added claim 17-19 have been entered. Claims 1-2, 4-6, 8-9, 12, 15, and 17-19 are now pending.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-2, 4-6, and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wung et al. (US 5623931) in view of Elkins (US 4869259).

4. Addressing claims 1 and 5, Wung discloses a system for computer aided surgery navigation (see col. 1 lines 10-30) which includes a sensor adapted to sense position of

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a needle attached by a reference frame to an item used in surgery (see col. 1 lines 30-50 and figs. 1 and 6) and a computer functionality adapted to receive information from the sensor about position of needle and generate information corresponding to position and orientation of the item to which the needle is attached (see col. 1 lines 10-50)

wherein: the reference frame comprises a receiving slot formed integral with the reference frame, the receiving slot defined by a side wall extending along three sides of the receiving slot to define a receiving opening configured to receive a mating portion attached to the item used in surgery, the receiving slot thus having a bottom portion formed by the reference frame, three side portions formed by the side wall, a receiving opening within the side wall, and an open top portion opposite of the bottom portion and in addition to the receiving opening on the side wall, such that all surfaces within the receiving slot are exposed, and the bottom of the receiving slot further comprising a key-hole (see col. 2 lines 22-50); the system further including a registering and securing mechanism attached to the item, comprising a mating portion configured to engage the receiving slot of the reference frame through the receiving opening and further configured such that the registering and securing mechanism may move within the receiving slot only along a single translational degree of freedom and further comprising a locking member configured to engage the key-hole and securely fix the mating portion within the receiving slot along the single translational degree of freedom (see col. 2 lines 22-50); wherein the needle may only attach in a determined position so that they may be removed from the item and reattached without incorrect registration of the needle relative to the item (see abstract, col. 1 lines 30-50, and col. 4 lines 1-17); and wherein

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the registering and securing mechanism includes a structure which allows the needle to be selectively attached and detached from the item (see abstract and col. 1 lines 30-50). Wung discloses that the apparatus may be used for biopsy and that the ultrasound imaging device is used to visualize the needle during surgery. Elkins discloses a needle that may be used in biopsy that is designed with an echogenic indicia used in guiding a biopsy using an ultrasonic imaging device; Elkins also discloses that it is desirable to know the absolute location of the tip of the needle and provides indicia for this purpose (see col. lines 10-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Wung by incorporating the indicia, as taught by Elkins, to improve the biopsy procedure by improving the visualization of the needle.

5. Addressing claims 2 and 6, Elkins discloses wherein at least one of the indicia includes a reflective surface adapted to be sensed by an infrared sensor device or a transponder that emits energy when interrogated (see col. lines 10-62). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify Wung by incorporating the indicia, as taught by Elkins, to improve the biopsy procedure by improving the visualization of the needle.

6. Addressing claim 4 and 8, Wung discloses in which the registering and securing mechanism comprises at least one of a ball plunger, a retractable plunger, a male pin and female receptor, or a magnetic device (see col. 2 lines 22-50).

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7. Addressing claim 9, Wung and Elkins disclose all the limitations as above for claims 1 and 9. Wung discloses that the apparatus may be used for biopsy and that the ultrasound imaging device is used to visualize the needle during surgery. Elkins discloses a needle that may be used in biopsy that is designed with an echogenic indicia used in guiding a biopsy using an ultrasonic imaging device; Elkins also discloses that it is desirable to know the absolute location of the tip of the needle and provides indicia for this purpose. Therefore the steps/limitations as set forth in the instant claim are disclosed by the combination of Wung and Elkins.

8. Claims 12, 15, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wung and Elkins, in view of Furia (US 7241267).

9. Addressing claims 12, 15, and 17-19, Furia discloses an ultrasonic needle guide device that includes an adjustable securing mechanism is interposed between the registering and securing mechanism and the item, the adjustable securing mechanism including structure which allows the registering and securing mechanism to be selectively repositioned relative to the item along three rotational degrees of freedom, in which the adjustable securing mechanism includes an adjustable rod with a base thumb screw for securing the adjustable rod (see figs. 1 and 13-14 and col. 11 line 52-col. 12 line 16). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to incorporate the limitations as taught by Furia to facilitate positioning the needle for better visualization and performance.

***Response to Arguments***

10. Applicant's arguments with respect to claims 1-2, 4-6, 8-9, 12, 15, and 17-19 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIGEL FONTENOT whose telephone number is

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(571)270-7032. The examiner can normally be reached on Monday-Friday (7:00a-4:00p).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. F./  
Examiner, Art Unit 3768

/Long V Le/  
Supervisory Patent Examiner, Art Unit 3768